IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	William W. Cimino	Examiner:	Catherine S. Williams
Serial No.:	10/600,118	Group Art Unit:	3763
Filed:	June 20, 2003	Docket. No.:	40206.19-US-U1
Title:	"Precision Fluid Delivery System and Method for Surgical Procedures"		

CERTIFICATE UNDER 37 CFR 1.8:

I hereby certify that this correspondence is being transmitted electronically to the U.S. Patent Office on July 30, 2007.

By:_____
Jenifer Weck

RESPONSE

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action mailed January 30, 2007, please amend the above-identified application as follows:

Amendments to the Claims begin on page 2 of this paper.

Remarks/Arguments begin on page 5 of this paper.

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application. Please amend the claims as follows:

Listing of Claims:

1. (Previously Presented) A system for accurately and rapidly delivering sterile fluids for use in a cosmetic surgery procedure comprising:

a strain gauge sensor;

a container of sterile fluid connected to the strain-gauge sensor so that the strain-gauge sensor will generate an electrical output proportional to the weight of the fluid and container from time-to-time;

a pump for pumping fluid from the container and having adjustable speed control for delivery of fluids within the range of 30 ml/min to 1000 ml/min;

a sterile tubing set connected to the fluid source and the pump for delivery of the sterile fluid during the surgical procedure;

a processor for processing the electrical output from the strain gauge from time-to-time to determine the amount of fluid delivered to the surgical procedure; and

a display for displaying the amount of fluid delivered during the surgical procedure.

2. (Original) The system of Claim 1 wherein the cosmetic surgery procedure is a member of the group consisting of lipoplasty and the filling of breast implants or sizers.

3. (Original) The system of Claim 1 wherein the pump is a peristaltic pump.

4. (Original) The system of Claim 1 wherein the display includes a reset button that will 'zero' the display when pressed.

5. (Original) The system of Claim 1 wherein the tubing set is made of polyvinyl chloride.

6. (Original) The System of Claim 1 wherein the display shows the amount of fluid in either weight or volume.

7. (Original) The system of Claim 2 wherein the pump is a peristaltic pump.

8. (Original) The system of Claim 2 wherein the tubing set is made of polyvinyl chloride.

9. (Original) The system of Claim 2 wherein the display shows the amount of fluid in either weight or volume.

10. (Previously Presented) A method for accurately and rapidly delivering sterile fluids for use in a cosmetic surgery procedure comprising:

supporting a container of sterile fluid from a strain-gauge sensor so that the strain-gauge sensor provides an electronic signal indicative of the weight of the container and sterile fluid from time-to-time;

connecting one end of a sterile tubing set to the fluid container and passing the tubing set through a pump so that the pump can remove sterile fluid from the container within the range of 30 ml/min to 1000 ml/min;

making the other end of the sterile tubing set available for delivery of the sterile fluid by the pump to the cosmetic surgery procedure;

activating the pump to pump fluid from the fluid source to the patient or the implantable device at a desired flow rate;

processing the electronic signal from the strain gauge to display the amount of sterile fluid removed from the container from time-to-time; and

monitoring the amount of sterile fluid pumped to the cosmetic surgery procedure;

releasing the pump activation when the desired amount of sterile fluid has been provided for the cosmetic surgery procedure.

11. (Original) The method of Claim 9 wherein the supporting of the container is accomplished by hanging the container from the strain-gauge.

12. (Original) The method of Claim 9 wherein the cosmetic surgery procedure is a member of the group consisting of lipoplasty and the filling of breast implants or sizers.

13. (Original) The method of Claim 9 wherein the pump is a peristaltic pump.

14. (Original) The method of Claim 9 wherein the tubing set is made of polyvinyl chloride.

15. (Original) The method of Claim 9 wherein the display shows the amount of fluid in either weight or volume.

16. (Original) The method of Claim 12 wherein the pump is a peristaltic pump.

17. (Original) The method of Claim 12 wherein the tubing set is made of polyvinyl chloride.

18. (Original) The method of Claim 12 wherein the display shows the amount of fluid in either weight or volume.

REMARKS/ARGUMENTS

This Amendment and the following remarks are intended to fully respond to the Office Action mailed January 30, 2007. In that Office Action, claims 1-18 were examined, and all claims were rejected. More specifically, Claims 1-4, 6, 7, and 9-13, 15-16, and 18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wheeldon et al. (USPN 4,670,007) in view of Hadzic et al. (USPN 5,910,135); and claims 5, 8, 14, and 17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Wheeldon in view of Hadzic, and further in view of general knowledge in the art. Reconsideration of these rejections, as they might apply to the original and amended claims in view of these remarks, is respectfully requested.

No claims have been amended, canceled, or newly added. Therefore, claims 1-18 remain present for examination.

Claim Rejections – 35 U.S.C. § 103

Claims 1-4, 6, 7, and 9-13, 15-16, and 18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wheeldon et al. (USPN 4,670,007) hereinafter "Wheeldon" in view of Hadzic et al. (USPN 5,910,135) hereinafter "Hadzic." Applicant respectfully traverses this rejection, because each of Wheeldon and Hadzic have teachings that would guide a person of ordinary skill in the art away from their combination.

As described previously, the claims in the present application are directed to systems and methods of accurately and rapidly delivering sterile fluids for use in a cosmetic surgery procedure, such as lipoplasty or filling of saline breast implants. These claimed systems are significantly different than systems used for intravenous (IV) delivery of fluids to a patient. IV systems are too slow and do not provide sufficient pressure to infuse fatty tissues, as would be necessary in lipoplasty. *See Specification*, page 2, line 20-page 3, line 2. As a consequence, the use of an IV system to deliver fluids for surgical procedures requiring rapid delivery of fluids would result in unduly prolonged operations and undue patient trauma. *See Id.*

The Office Action alleges that Wheeldon teaches a system that "is capable of being used during any type of surgical procedure that would require a rapid administration of fluids." *Office Action* (1/30/07), page 2. Applicant respectfully disagrees. As would be appreciated by someone of ordinary skill in the art, the Wheeldon system is only capable of being used for very

slow and precise administration of fluids such as IV drug delivery. The system would be useless in the cosmetic procedures that are the focus of the present application. For example, the Wheeldon system would not be capable of rapidly delivering fluids for filling saline breast implants or generating sufficient pressure to infuse fatty tissues as is necessary in lipoplasty. Accordingly, the statement that the Wheeldon system "is capable of being used during any type of surgical procedure that would require a rapid administration of fluids" is not accurate.

The Office Action concedes that Wheeldon does not teach all the elements of the claims, and in particular fails to teach a pump capable of delivering fluid within the claimed ranges. However, the Office Action asserts that "Hadzic discloses such a flow rate for intraveneous infusion if a high flow rate is needed due to intraoperative bleeding, etc." *Office Action* (1/30/07), page 2. Thus the Office Action alleges that the combination of Wheeldon and Hadzic renders obvious the pending claims. Applicant respectfully disagrees, because each of the references teaches away from combination with the other.

Wheeldon discloses a fluid dispensing system for delivering fluid under the control of a flow controller or peristaltic pump. In describing problems with other systems, Wheeldon clearly distinguishes from drip systems such as those disclosed by Hadzic. For example, in the background section, Wheeldon states:

> ***Normal gravity infusion***, although low in cost owing to the use of mass-produced disposable standard administration sets, ***is totally unsuitable for precisely controlled infusions*** because the accuracy of delivery cannot be practically controlled even with the aid of a conventional flow controller. Similarly, ***the "drip-rate" type of device***, over which control is maintained by counting drops, is capable of providing an accurate drop delivery rate, often with standard administration sets, but ***cannot provide volumetric accuracy owing to the wide variation in drop sizes***.

Wheeldon, column 1, lines 42-53 (emphasis added). As this language makes clear, Wheeldon teaches away from gravity infusion and drip systems, because of their inability to accurately control the amount and rate of fluid delivery. Indeed, the system of Wheeldon is specifically designed to address the shortcomings of gravity infusion and drip systems. *See Wheeldon*, column 3, lines 33-38 ("It is an object of the present invention to provide a fluid flow control process and apparatus which are adapted accurately to dispense fluid, at a selected delivery rate, from a fluid container through a delivery tube without requiring access to the fluid for monitoring purposes."). Accordingly, a person of ordinary skill in the art would be guided away from combining

Wheeldon with a drip or gravity infusion system as disclosed by Hadzic (described in detail below). The combination of Wheeldon and Hadzic is thus inconsistent with the teachings in Wheeldon.

In complete contrast to Wheeldon, the Hadzic patent teaches a drip IV system for use by anesthesiologists. It does not employ a pump, rather it is a gravity flow system. The system includes a separate "microflow path" and a "macroflow path" that can be operated separately or combined to produce a low flow rate or a higher flow rate. The "microflow" produces 60 drops/ml. and delivers 0.5 ml/min. to about 28 ml/min. of fluid. The "macroflow" produces 15 drops/ml. and delivers 4 ml/min. to about 75 ml/min. Hadzic physically combines them in one system including a "dual-sight drip chamber" to view either or both flows. The slow system is used for gradual provision of anesthetic or other medications, and the fast system is used to address sudden loss of fluids during an operation or other more emergent situations where a large dose of fluid is required temporarily.

Hadzic distinguishes its system from "infusion" systems that mechanically provide a variable flow rate, such as the Wheeldon system. Hadzic notes with respect to infusion systems:

> Several flow rate regulators, such as the Abbott Laboratories' Dial-A-Flow, see U.S. Pat. No. 3,877,428 have been introduced in recent years in attempts to overcome the aforementioned disadvantages associated with the use of conventional roller clamps and infusion procedures. U.S. Pat. No. 5,019,055 is yet another invention designed in order to improve the accuracy of delivering the desired flow rate and is said to represent an advantage of the aforementioned Dial-A-Flow device.
>
> However, since anesthesia providers routinely work in an intense and dynamic environment prone to human mistakes, any unnecessary complexity of the equipment used during administration of anesthesia introduces a risk of a mishap. These systems are also designed to provide a wide range of flow rates through a single drip chamber. Since the capillary tube in this singular drip chamber has to be of a large diameter, this results in a very slow droplet formation when a slow infusion rate is selected. ***This again, precludes monitoring of the flow rate and prevents the operator from assuring continuous flow by observing the rate of drops formation, which is the most common and convenient method of monitoring of IV flow used by anesthesiologists. The ability to observe flow rate and adjust it accordingly is far more important in anesthesia practice than the limitation of flow provided by these infusion devices. Consequently, none of these devices have been widely accepted in anesthesia practice.*** Thus, the present invention also provides a means of avoiding the mixing or flow from one path to another by having separate drip chambers and flow paths at the same height in one enclosure.

Hadzic, col. 4, lines 24-53 (emphasis added). As the quoted language indicates, Hadzic considers the ability of a user to observe the rate as critically important. Accordingly, these teachings would guide a person of ordinary skill in the art away from using a system that does not enable the user to monitor the formation of drips, such as the Wheeldon system. The combination of Wheeldon and Hadzic is thus inconsistent with the teachings in Hadzic.

Claims 1-4, 6, 7, and 9-13, 15-16, and 18 are therefore not obvious in view of Wheeldon and Hadzic. Both of the references have teachings that are inconsistent with their combination. Wheeldon teaches away from using a drip system as disclosed by Hadzic, and Hadzic teaches away from the use of a mechanically variable flow control, such as a used by Wheeledon.

Claims 5, 8, 14, and 17 also stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wheeldonin in view of Hadzic, and further in view of general knowledge in the art. As described above, claims 1 and 10 are not obvious in light of Wheeldon and Hadzic. Claims 5, 8, 14, and 17 depend upon one of claims 1 and 10 and are not obvious for the same reasons as discussed above with respect to claims 1 and 10.

Conclusion

This Response fully replies to the Office Action mailed on January 30, 2007. Still, the Office Action may contain arguments and rejections that are not directly addressed by this Amendment because they are rendered moot in light of the preceding arguments in favor of patentability. Hence, failure of this Response to directly address an argument raised in the Office Action should not be taken as an indication that the Applicant believes the argument has merit. Additionally, failure to address statements/comments made in the Office Action does not mean that the Applicant acquiesces to such statements or comments. Furthermore, the claims of the present application may include other elements, not discussed in this Response, which are not shown, taught, or otherwise suggested by the art of record. Accordingly, the preceding arguments in favor of patentability are advanced without prejudice to other bases of patentability.

It is believed that no fees are due with this Response. However, the Commissioner is hereby authorized to charge any deficiencies or credit any overpayment with respect to this patent application to deposit account number 13-2725.

In light of the above remarks, it is believed that the application is now in condition for allowance and such action is respectfully requested. Should any additional issues need to be resolved, the Examiner is requested to telephone the undersigned to attempt to resolve those issues.

In light of the above remarks and amendments, it is believed that the application is now in condition for allowance and such action is respectfully requested. Should any additional issues need to be resolved, the Examiner is requested to telephone the undersigned to attempt to resolve those issues.

Respectfully submitted,

Dated: July 30, 2007

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